UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MARK A. CORBAN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. SAREPTA THERAPEUTICS, INC., CHRIS GARABEDIAN, SANDY MAHATME, and ED KAYE, Defendants.	CIVIL ACTION NO. 14-CV-10201-IT

PLAINTIFFS' NOTICE OF RECENT DEVELOPMENTS

Lead Plaintiffs Mark Corban and Steve Fleischmann ("Plaintiffs") submit this Notice of Recent Developments in this securities class action lawsuit on behalf of purchasers of Sarepta Therapeutics, Inc. ("Sarepta" or the "Company') securities during the period July 10, 2013 through November 11, 2013 (the Class Period"). This Notice of Recent Developments pertains to the allegations of Plaintiffs' Consolidated Complaint filed July 21, 2014 (Dkt. No. 39) and issues and arguments raised in the Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Amended Complaint filed August 18, 2014 (Dkt. No. 43) ("Def. Br."), Plaintiffs' Corrected Memorandum of Law in Opposition to Defendants' Motion to Dismiss (Dkt. No. 49) ("Pl. Br."), and the Reply Brief in Support of Defendants' Motion to Dismiss Plaintiffs' Amended Complaint filed October 10, 2014 (Dkt. No. 59) ("Def. Reply").

Plaintiffs allege claims against Defendants for violations of Sections 10(b) and 20(a) of the Securities Exchange Act (the "Exchange Act") and Securities and Exchange Commission ("SEC")

Rule 10b-5. More specifically, Defendants[1] are alleged to have made numerous false and/or misleading statements during the period July 10, 2013 through November 11, 2013 concerning, among other things: the prospects that the Food and Drug Administration ("FDA") would accept a New Drug Application ("NDA") for eteplirsen based on Sarepta's Phase IIb trial data set; the significance of the Phase IIb data set; and the purported clarity and certainty of the FDA's guidance concerning same.

A. Recent Developments

Since the filing of the Consolidated Complaint and the conclusion of the briefing on Defendants' Motion to Dismiss, additional developments have transpired, which support Plaintiffs' claims against the Defendants:

Sarepta's October 27, 2014 Press Release

On October 27, 2014, Sarepta issued a press release updating the market on Sarepta's discussions with the FDA regarding Sarepta's planned NDA submission for the approval of eteplirsen for the treatment of DMD. *See* Exhibit 1, attached hereto. The release revealed that during the previous week Sarepta had received meeting minutes describing "additional data…now required as part of the NDA submission" and that "[b]ased on these requests, Sarepta plans to submit an NDA by mid-year 2015, pending any additional requests from further discussions with the FDA." *Id.* The release set forth certain excerpts from the Pre-NDA Meeting Minutes related to information that the FDA is requesting:

> *"The sponsor should include 3-month data from at least 12 to 24 newly exposed patients at the time the NDA is submitted."*

[1] Sarepta Therapeutics Inc. ("Sarepta" or the "Company"); Chris Garabedian ("Garabedian"), President, Chief Executive Officer ("CEO"), and director of Sarepta; Sandy Mahatme ("Mahatme"), Senior Vice President and Chief Financial Officer ("CFO") of Sarepta; and Ed Kaye ("Kaye"), Senior Vice President and Chief Medical Officer ("CMO") of Sarepta.

> *"Available data from the other patients enrolled in the new eteplirsen studies (studies 301, 203, 204) should also be included at the time the NDA is submitted, even if exposure is less than 3 months in duration."*
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> *"Additional data from later time points and from newly enrolled patients should be submitted in the 120-Day Safety Update."*
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> *"FDA strongly advises the sponsor to obtain and submit patient-level natural history data. FDA is prepared to appeal to the academic groups holding the data to allow the sponsor a means to acquire the data."*
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> *"The study 201/202 clinical site inspection conducted in May, 2014, after the issuance of the April 15, 2014, guidance letter, uncovered marked disparities in the immunohistochemistry methodology and concerns about the reproducibility of the data. The lack of confirmation of robust dystrophin measurement during the site visit necessitates including the independent assessment of dystrophin-positive fibers and 168-week efficacy data from study 201/202 in the NDA."*
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> *"FDA strongly urged the sponsor to submit the MRI data with appropriate natural history controls."*
>
> The FDA also stated that *"[a]dditional discussion between the sponsor and the FDA will be necessary to determine what would constitute a complete NDA."*

Id. (emphasis in original).

The press release demonstrates the severe level at which Sarepta's trial and dataset was lacking. For example, the press release reveals that Sarepta has failed to provide the FDA with "patient-level natural history data." *Id.* Further, the press release contradicts Defendants' argument that "[w]hat the Company believed and disclosed to investors in July [2013] turned out in April of this year to be exactly right." Def. Br. at 6. In truth, more than one year after Defendants' statements that "feedback from the FDA confirms [that] our Phase IIB study data set is sufficient for them to consider an NDA filing" (¶75; *see also* ¶¶80, 84), the FDA is still unwilling to consider an NDA filing based on numerous crucial deficiencies in Sarepta's dataset for eteplirsen.

The FDA's October 30, 2014 Statement

On October 30, 2014 the FDA issued a release entitled "Duchenne Muscular Dystrophy Statement," attached hereto at Exhibit 2. This unusual statement by the FDA was issued in response, in part, to Sarepta's October 27th release and provided in part:

> To the extent allowed by laws restricting release of confidential information about experimental drugs, FDA is addressing questions the agency has received from DMD patients, their families, and others in the community who are concerned about the timing of the filing of an NDA for eteplirsen.
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> ***Over the past several years, FDA has worked extensively with Sarepta on the development of eteplirsen, and provided guidance with respect to the data that would be necessary to determine whether it is effective and support filing of an NDA.*** Following a meeting with FDA last April, Sarepta announced on April 21, 2014, that "with additional data to support the efficacy and safety of eteplirsen for the treatment of DMD, an NDA should be fileable." Sarepta also announced at that time that FDA had communicated that there were areas of concern in the existing database, and that FDA had provided Sarepta with "examples of additional data and analyses that, if positive, would be important to enhance the acceptability of an NDA filing…." Sarepta announced at the time its plans to submit an NDA for eteplirsen by the end of 2014.
>
> Since the April 2014 meeting, FDA has been working intensively to help Sarepta provide the additional data and analyses needed to support an NDA. FDA understands the considerable disappointment in the Duchenne community following Sarepta's October 27 announcement that the previous time frame for submitting the NDA for eteplirsen cannot be met.
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> ***In its advice to Sarepta, FDA has consistently stated that it would be necessary to include data in its NDA demonstrating that eteplirsen increases production of the muscle protein dystrophin.*** (Eteplirsen's proposed mechanism of action is through increasing production of this muscle protein.) As described by Sarepta in its October 27 statement, the need for additional data and analyses to support the NDA was reinforced by an FDA inspection of the clinical site where dystrophin analyses had been conducted. It is important to note that the agency did not find any evidence of fraud at this site, as has been perceived by some. FDA is concerned that the methods used to measure dystrophin were not adequately robust to support an NDA submission. Thus, FDA provided Sarepta with detailed recommendations on how to improve these dystrophin analyses, and FDA's most recent advice was consistent with the advice provided after the April 2014 meeting.

> ***FDA has also been consistent in its guidance to Sarepta that it would be necessary to submit data from the ongoing open-label trial of eteplirsen (Study 202) in an NDA, along with data from natural history studies that could show that patients treated with eteplirsen experienced slower decline in physical function.*** FDA has worked closely with Sarepta in efforts to obtain these natural history data from investigators.
>
> ***FDA has consistently advised Sarepta that data from additional patients, beyond the patients included in Study 202, would be critical to our assessment of the safety and efficacy of eteplirsen.*** In our April 2014 letter to Sarepta, FDA strongly encouraged Sarepta to begin enrollment of new patients as soon as possible.

Id. (emphasis added).

Thus, as represented by the agency itself, the FDA has been "consistent" in its guidance to Sarepta as to what significant additional data would be necessary to submit before the FDA would consider an NDA submitted for filing by the Company. It is clear that these additional data requirements represented a significant obstacle to both the FDA's acceptance and approval of an NDA for eteplirsen. Defendants' arguments that investors were sufficiently warned of these risks by Sarepta's innocuous and isolated disclosure that the FDA had requested additional information about Sarepta's dystrophin quantification methodology (Def. Reply at 3, 5-6, 9, 12-13) is without merit, as the identified risk warnings were insufficient to counter-balance the misleading impression created by Defendants. Indeed, despite the FDA's actual guidance, Defendants repeatedly informed investors in no uncertain terms that the FDA had advised the Company that the agency was "open to considering an NDA filing ***based on the data we've shared with them***" and that the "***Phase II data set is sufficient for [the FDA] to consider an NDA filing***." ¶¶75, 84 (emphasis added); *see also* ¶¶71, 80. At a minimum, Defendants' statements were materially misleading in that Defendants knew or recklessly disregarded the FDA's "consistent" guidance that significant additional data was needed.

Dated: November 19, 2014

/s/ William B. Federman

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CERTIFICATE OF SERVICE

This is to certify that on November 19, 2014, I electronically transmitted this document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the counsel of record.

/s/ William B. Federman
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